IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC and FRESENIUS KABI DEUTSCHLAND GMBH, Plaintiffs, v. EUROHEALTH INTERNATIONAL SARL, Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Fresenius Kabi USA, LLC ("Fresenius Kabi") and Fresenius Kabi Deutschland GmbH ("Fresenius Deutschland") (collectively, "Fresenius" or "Plaintiffs") bring this action for patent infringement against Defendant Eurohealth International Sarl ("Eurohealth").

1. This is an action by Fresenius against Eurohealth for infringement of United States Patent No. 9,731,082 ("the '082 patent") and 9,248,229 ("the '229 patent"). This action arises out of Eurohealth's filing an amendment to its Abbreviated New Drug Application ("ANDA") No. 202159 to engage in the commercial manufacture, use, or sale of a generic version of Dilaudid® Injection 2 mg/mL prior the expiration of the '082 patent and the '229 patent.

THE PARTIES

2. Fresenius Kabi is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi currently sells, promotes, distributes, and markets Dilaudid® Injection in the United States and shares in the proceeds from the U.S. sales of the Dilaudid® Injection.

3. Fresenius Kabi Deutschland GmbH is a limited liability company organized and existing under the laws of Germany with a principal place of business at Else-Kröner-Str. 1, 61352 Bad Homburg, Germany. Fresenius Kabi Deutschland is the assignee and owner of all rights, title, and interest in the '082 and '229 patents.

4. On information and belief, Defendant Eurohealth is a company incorporated in Switzerland with a principal place of business at Rue des Battoirs 7, 1205 Geneve, Switzerland. On information and belief, Eurohealth presently owns ANDA No. 202159 and prepared and submitted the amendment to ANDA No. 202159 giving rise to this action.

JURISDICTION AND VENUE

5. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 1 *et seq*. generally and 35 U.S.C. § 271 specifically.

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Eurohealth because, on information and belief, Eurohealth has continuous and systematic contacts with the State of Delaware, regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in the State of Delaware, and intends to sell its ANDA Product in the State of Delaware. On further information and belief, Eurohealth regularly and continuously transacts business within the State of Delaware, including, but not limited to, shipping pharmaceuticals to West-Ward Pharmaceutical Corp., a corporation organized and existing under the laws of the State of Delaware, from locations outside the United States for distribution by West-Ward Pharmaceutical Corp. within the United States generally, and within this District specifically.

8. Alternatively, this Court has personal jurisdiction over Eurohealth because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Eurohealth is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Eurohealth has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Eurohealth's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Eurohealth satisfies due process.

9. Additionally, this Court has personal jurisdiction over Eurohealth because it previously has been sued in this Judicial District, did not challenge this Court's exercise of personal jurisdiction over it, and availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, Hospira, Inc. et al. v. Eurohealth International Sarl et al*., C.A. No. 14-1008-GMS; *Cephalon, Inc. v. Eurohealth International Sarl et al.*, C.A. No. 14-1045-GMS.

10. Venue is proper in this District for Eurohealth pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Eurohealth is a company organized and existing under the laws of Switzerland and may be sued in any judicial district. 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT

11. The '082 patent, entitled "Drug Container," was duly and legally issued on August 15, 2017, naming Michel Vernizeau, Cedric Foucher, and Lionel Lefebvre as the inventors. A true and correct copy of the '082 patent is attached hereto as Exhibit A.

12. The '229 patent, entitled "Packaging System for Oxygen-Sensitive Drugs," was duly and legally issued on February 2, 2016, naming Thomas Devouassoux, Eric Forat, and

James Kenneth Proctor as the inventors. A true and correct copy of the '229 patent is attached hereto as Exhibit B.

13. Plaintiff Fresenius Kabi Deutschland is the assignee and lawfully owns all rights, title, and interest in the '082 and the '229 patents, including the right to sue and to recover for past infringement thereof.

14. The FDA issues a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book").

15. Fresenius Kabi is the holder of New Drug Application ("NDA") No. 019034 for Dilaudid® Injection, which the FDA approved on April 30, 2009. In accordance with 21 U.S.C. § 355(b)(1), the '082 patent and '229 patent are listed in the Orange Book in connection with approved NDA No. 019304, as patents "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale" of Fresenius Kabi's NDA drug product.

16. Fresenius Kabi currently sells Dilaudid® Injection in the United States. The '082 patent is currently not due to expire until April 23, 2032 and the '229 patent is currently not due to expire until March 12, 2034.

EUROHEALTH'S ANDA NO. 202159

17. On information and belief, Eurohealth submitted an amendment to ANDA No. 202159 to the FDA to engage in the commercial manufacture, use, importation, offer for sale, or sale of generic Dilaudid® Injection (hydromorphone hydrochloride) 2 mg/mL (the "ANDA Product").

18. On information and belief, ANDA No. 202159 contains Paragraph IV certifications that the '082 patent and '229 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

19. On information and belief, Eurohealth is the owner of ANDA No. 202159.

20. On information and belief, ANDA No. 202159 has been approved by the FDA before the expiration of the '082 and '229 patents, and thus Eurohealth will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA product, despite the '082 patent and the '229 patent.

21. On information and belief, Eurohealth was aware of the '082 patent and the '229 patent when the amendments to ANDA No. 202159 were submitted to the FDA, containing the above-described Paragraph IV certifications.

22. Eurohealth notified Fresenius of the Paragraph IV certifications to the '082 patent and the '229 patent in a letter dated April 18, 2018 ("Eurohealth's Notice Letter"). Attached to Eurohealth's Notice Letter was a two-page document entitled "Detailed Statement" that allegedly sets forth Eurohealth's statement of factual and legal basis that the '082 patent and the '229 patent would not be infringed ("Eurohealth's Detailed Statement"). Fresenius received Eurohealth's Notice Letter and Eurohealth's Detailed Statement by Federal Express shipment on April 19, 2018.

23. According to applicable regulations, Eurohealth's Detailed Statement must contain the factual and legal basis for the applicant's opinion that the patent is invalid, unenforceable, or not infringed which includes a claim-by-claim analysis, describing "for each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "for each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." *See* 21 CFR § 314.95(c); *see also* 21 CFR § 314.52.

24. Despite the applicable regulations, Eurohealth's Detailed Statement failed to address nearly all claim limitations present in the '082 patent and the '229 patent. Additionally,

Eurohealth's Detailed Statement did not raise allegations of invalidity of the '082 patent or the '229 patent.

25. Eurohealth's Notice Letter included an "Offer of Confidential Access to Application" pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). Subsequent to Eurohealth's Offer of Confidential Access to Application, representatives of Fresenius and Eurohealth negotiated a mutually agreeable Offer of Confidential Access to Application that imposed mutually-agreeable terms, restrictions, and limitations. On May 2, 2018, Fresenius executed the jointly negotiated Offer of Confidential Access to Application (the "Executed OCA").

26. After signing the Executed OCA, Eurohealth provided only 48 pages of its ANDA No. 202159 to Fresenius. Eurohealth's 48-page production pursuant to the Executed OCA failed to provide Fresenius with sufficient information needed to fully evaluate Eurohealth's conclusory claim of non-infringement contained in Eurohealth's Detailed Statement.

27. Fresenius made numerous attempts to obtain information necessary to evaluate Eurohealth's non-infringement claims. Specifically requesting the production of a full copy of ANDA No. 202159, correspondence between Eurohealth and the FDA concerning ANDA No. 202159 and the ANDA product, and samples of the finished dosage form of the ANDA product. Despite the protections provided by the Executed OCA, Eurohealth refused to produce any additional information.

28. Therefore, on information and belief, Eurohealth failed to address several claim limitations of the claims of the '082 patent and '229 patent in Eurohealth's Detailed Statement, despite the applicable regulations, and Eurohealth has denied Fresenius' attempts to receive

additional information necessary to evaluate fully Eurohealth's ANDA Product under the Executed OCA.

29. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and due to the lack of information provided by Eurohealth, despite the Executed OCA, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm its allegations of infringement and to present to the Court evidence that Eurohealth's ANDA Products fall within the scope of the claims of the '082 patent and the '229 patent.

COUNT I: INFRINGEMENT OF THE '082 PATENT

30. The allegations of paragraphs 1-29 are realleged and incorporated herein by reference.

31. The submission of the amendment to ANDA No. 202159 including a Paragraph IV certification regarding the '082 patent was an act of infringement by Eurohealth of one or more claims of the '082 patent under 35 U.S.C. § 271(e)(2).

32. On information and belief, Eurohealth's ANDA Product, as described ANDA No. 202159, is covered by at least claim 1 of the '082 patent. Thus, on information and belief, Eurohealth's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Product before the expiration of the '082 patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '082 patent.

33. On information and belief, Eurohealth has infringed the '082 patent by submitting and maintaining the amended ANDA No. 202159 before the FDA to market Eurohealth's ANDA Product before the expiration of the '082 patent.

34. On information and belief, Eurohealth actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of the amended ANDA No. 202159 to the FDA.

35. On information and belief, Eurohealth induced the infringement of the '082 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of the amended ANDA No. 202159 with the Paragraph IV Certification and in the preparation to sell Eurohealth's ANDA Product in the United States.

36. On information and belief, Eurohealth intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product immediately and imminently.

37. On information and belief, Eurohealth plans and intends to, and will, actively induce infringement of the '082 patent immediately and imminently.

38. On information and belief, Eurohealth knows that its ANDA Product is especially made or adapted for use in infringing the '082 patent and that Eurohealth's ANDA Product is not a staple article of commerce suitable for substantial noninfringing use. On information and belief, Eurohealth plans and intends to, and will, contribute to the infringement of the '082 patent immediately and imminently.

39. Fresenius will be substantially and irreparably harmed by Eurohealth's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Eurohealth is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Eurohealth's ANDA Product.

40. Eurohealth's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '229 PATENT

41. The allegations of paragraphs 1-40 are realleged and incorporated herein by reference.

42. The submission of the amendment to ANDA No. 202159 including a Paragraph IV certification regarding the '229 patent was an act of infringement by Eurohealth of one or more claims of the '229 patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, Eurohealth's ANDA Product, as described ANDA No. 202159, is covered by at least claim 1 of the '229 patent. Thus, on information and belief, Eurohealth's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Product before the expiration of the '229 patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '229 patent.

44. On information and belief, Eurohealth has infringed the '229 patent by submitting and maintaining the amended ANDA No. 202159 before the FDA to market Eurohealth's ANDA Product before the expiration of the '229 patent.

45. On information and belief, Eurohealth actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of the amended ANDA No. 202159 to the FDA.

46. On information and belief, Eurohealth induced the infringement of the '229 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of the amended ANDA No. 202159 with the Paragraph IV Certification and in the preparation to sell Eurohealth's ANDA Product in the United States.

47. On information and belief, Eurohealth intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Product immediately and imminently.

48. On information and belief, Eurohealth plans and intends to, and will, actively induce infringement of the ’229 patent immediately and imminently.

49. On information and belief, Eurohealth knows that its ANDA Product is especially made or adapted for use in infringing the ’229 patent and that Eurohealth’s ANDA Product is not a staple article of commerce suitable for substantial noninfringing use. On information and belief, Eurohealth plans and intends to, and will, contribute to the infringement of the ’229 patent immediately and imminently.

50. Fresenius will be substantially and irreparably harmed by Eurohealth’s infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Eurohealth is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Eurohealth’s ANDA Product.

51. Eurohealth’s activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Eurohealth has infringed the ’082 patent and the ’229 patent under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the FDA withdraw its approval of Eurohealth’s ANDA and the effective date of any FDA approval of Eurohealth’s ANDA shall be no earlier the last expiration date of the ’082 patent or ’229 patent;

(C) Entry of a permanent injunction enjoining Eurohealth, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Eurohealth or on its behalf from commercially manufacturing, using, offering for sale, or selling

its ANDA Product within the United States, or importing its ANDA Product into the United States, until the day after the last expiration date of the ’082 patent or the ’229 patent;

(D) A judgment declaring that making, using, selling, offering to sell, or importing Eurohealth’s ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the ’082 patent and/or the ’229 patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(E) A declaration under 28 U.S.C. § 2201 that if Eurohealth, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Eurohealth’s ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

(F) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Eurohealth engages in the commercial manufacture, use, offer for sale, sale, and/or importation of its ANDA Product, or any product that infringes the ’082 patent and/or the ’229 patent, or induces or contributes to such conduct, prior to the expiration of the patents;

(G) A finding that this is an exceptional case, and an award of attorneys’ fees in this action pursuant to 35 U.S.C. § 285;

(H) Costs and expenses in this action; and

(I) Such other and further relief as the Court deems just and proper.

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